May 20, 2021

Kenpax International Limited
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K202899
Trade/Device Name: Procedure Mask/Surgical Mask (Ear loops and Tie-on)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 8, 2021
Received: February 11, 2021

Dear Ivy Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Clarence W. Murray III, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K202899

Device Name
Procedure Mask/ Surgical Mask
Ear loops and Tie-on

Indications for Use *(Describe)*
The Procedure Masks/ Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(K) Summary**
**K202899**

Date of summary prepared: 2021-05-20

**A. Applicant:**

KENPAX INTERNATIONAL LIMITED
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**B. Device:**

Trade Name: Procedure mask/ Surgical Mask
Common Name: SURGICAL MASK
Model: ear loops & Tie-on

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

**C. Predicate device:**

K133070
Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G
Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G
BH Medical Products Co., Ltd.

**D. Indications for use of the device:**

The Procedure Masks/ Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

**E. Device Description:**

The Procedure Masks (68-8506-G (Green, ear loop, level 1) & 68-8508-G (Green, ear loop, level 3) are single use, three-layer, flat-folded masks with ear loops, and nose wire. The Procedure Masks are manufactured with three layers, the inner and outer layers are made of spun- bond polypropylene, and the middle layer is made of meltblown polypropylene filter.

The ear loops welded are used to keep the mask close to the mouth and the nose. The elastic ear loops are not made with natural rubber latex. The nose wire is to allow the user to fit the facemask around their nose, which is made of polyethylene wire. The procedure masks will be provided in green.

The Surgical Masks (68-8536-B (Blue, tie-on, level 1) & 68-8538-B (Blue, tie-on, level 3) are single use, three-layer, flat-folded masks with Ties, and nose wire. The Surgical Masks are manufactured with three layers, the inner and outer layers are made of spun- bond polypropylene, and the middle layer is made of meltblown polypropylene filter.

The ties welded are used to keep the mask close to the mouth and the nose. The tie is made of spunbond polypropylene. The nose wire is to allow the user to fit the facemask around their nose, which is made of polyethylene wire. The surgical masks will be provided in Blue.

The procedure mask/ surgical masks are sold non-sterile and are intended to be single use, disposable device.

The difference

Detailed information of the four models please see below table.

| Product Model | Feature | Layers (components) | Nose Wire | Earloop | Colorant |
|---|---|---|---|---|---|
| **68-8506-G ASTM Level 1** | Green Earloop | Outer: 22gsm SPP<br>Middle: 22gsm MB<br>Inner: 22gsm SPP | Polyethylene Coated Steel Wire | Polyester | Green masterbatch PCG861 |
| **68-8508-G ASTM Level 3** | Green Earloop | Outer: 25gsm SPP<br>Middle: 25gsm MB<br>Inner: 25gsm SPP | Polyethylene Coated Steel Wire | Polyester | Green masterbatch PCG861 |
| **68-8536-B ASTM Level 1** | Blue Tie-on | Outer: 22gsmSPP<br>Middle: 22gsmMB<br>Inner: 22gsmSPP | Polyethylene Coated Steel Wire | 40gsm SPP | Blue masterbatch PCB1628 |
| **68-8538-B ASTM Level 3** | Blue Tie-on | Outer: 25gsmSPP<br>Middle: 25gsmMB<br>Inner: 25gsmSPP | Polyethylene Coated Steel Wire | 40gsm SPP | Blue masterbatch PCB1628 |

**F. Comparison with predicate device**

The procedure masks/surgical masks are essentially the same as or similar to the predicate device in terms of the intended use, design and construction, performance characteristics.

Table 1 General Comparison

| Device | Proposed Device | Predicate Device | Result |
|---|---|---|---|
| **510K #** | K202899 | K133070 | |
| **Manufacturer** | KENPAX INTERNATIONAL LIMITED | BH Medical Products Co., Ltd. | |
| **Model Name** | Procedure Mask/ Surgical Mask<br>Ear loops & tie-on | Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G<br>Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G | Similar |
| **Classification** | Class II Device, FXX (21 CFR878.4040) | Class II Device, FXX (21 CFR878.4040) | Same |
| **Intend Use/ Indications for Use** | The Procedure Masks/ Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile. | The surgical face masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile. | Same |
| **Materials** | | | |
| **Outer layer** | Spunbond Polypropylene<br>Level 1: 22gsm<br>Level 3: 25gsm | Spunbond Polypropylene | Same |
| **Inner layer** | Spunbond Polypropylene<br>Level 1: 22gsm<br>Level 3: 25gsm | Spunbond Polypropylene | Same |
| **Filter layer** | Melt-blown Polypropylene<br>Level 1: 22gsm<br>Level 3: 25gsm | Meltblown Polypropylene | Same |
| **Nose wire** | Polyethylene Coated Steel Wire | Aluminum Wire | Different |
| **Ear loops** | Nylon, spandex | Polyester | Different |
| **Tie-on** | Spunbond Polypropylene | Spunbond Polypropylene | Same |
| **Design Features** | Ear Loops, Tie-on | Ear Loops, Tie-On | Same |
| **Mask style** | Flat Pleated | Flat Pleated | Same |
| **Color** | Blue, green | Blue, Green | Same |
| **Dimension (Length)** | 178±5mm | 3.5”+/-0.25”<br>4.2”+/-0.25” | Similar |
| **Dimension (Width)** | 95±5mm | 6.8”+/-0.25” | Similar |

| | | | |
|---|---|---|---|
| **OTC use** | Yes | Yes | Same |
| **Sterility** | Non-Sterile | Non-Sterile | Same |
| **Use** | Single Use, Disposable | Single Use, Disposable | Same |
| Biocompatibility | Non-cytotoxic, Non-sensitizing, non-irritating | Non-cytotoxic, Non-sensitizing, non-irritating | Same |
| **Performance Testing (see Table 2)** | | | |
| **ASTM level** | Level 1, Level 3 | Level 1, Level 2, Level 3 | Similar |
| **Fluid Resistance** | Meet ASTM F1862-17 | Meet ASTM F1862-07 | similar |
| **Particulate Filtration Efficiency** | Meet ASTM F2299-17 | Meet ASTM F2299-03 | Similar |
| **Bacterial Filtration Efficiency** | Meet ASTM F2101-19 | Meet ASTM F2101-07 | Similar |
| **Differential Pressure** | Meet EN 14683: 2019, Annex C | Meet MIL-M36945C | Different |
| **Flammability** | Meet 16 CFR 1610 | Meet 16 CFR 1610 | Similar |
| Biocompatibility | Non-cytotoxic, Non-sensitizing, non-irritating | Non-cytotoxic, Non-sensitizing, non-irritating | Same |

Table 2 Comparison of Performance testing

| **Item** | **Proposed device** (K202899) | | **Predicate device (**K133070) | **Acceptance criteria (Level 1)** | **Result** |
|---|---|---|---|---|---|
| | Model 68-8506-G | Model 68-8536-B | | | |
| **Fluid Resistance** | 32 out of 32 passed at 80 mmHg, 3 lots | 32 out of 32 passed at 80 mmHg, 3 lots | Meet the ASTM F2100 Requirements for Level 1 Classification | 29 out of 32 pass at 80 mmHg | PASS |
| **Particulate Filtration Efficiency** | 97.4%, 97.5%, 97.5% | 97.2%, 97.1%, 97.1% | Meet the ASTM F2100 Requirements for Level 1 Classification | ≥95% | PASS |
| **Bacterial Filtration Efficiency** | 99.9% 3 lots | 99.9% 3 lots | Meet the ASTM F2100 Requirements for Level 1 Classification | ≥95% | PASS |
| **Differential Pressure** | 2.9, 2.8, 2.7 $mmH_2O/cm^2$ | 3.7, 3.4, 3.7 $mmH_2O/cm^2$ | Meet the ASTM F2100 Requirements for Level 1 Classification | ＜5.0 | PASS |
| **Flammability** | Class 1 | Class 1 | Class 1 | Class 1 | PASS |

| **Item** | **Proposed device** (K202899) | | **Predicate device (**K133070) | **Acceptance criteria (Level 3)** | **Result** |
|---|---|---|---|---|---|
| | Model 68-8508-G | Model 68-8538-B | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Fluid Resistance** | 32 out of 32 passed at 160 mmHg, 3 lots | 32 out of 32 passed at 160 mmHg, 3 lots | Meet the ASTM F2100 Requirements for Level 3 Classification | 29 out of 32 pass at 160 mmHg | PASS |
| **Particulate Filtration Efficiency** | 98.2%, 98.4%, 98.4% | 98.4%, 98.4%, 98.3% | Meet the ASTM F2100 Requirements for Level 3 Classification | ≥98% | PASS |
| **Bacterial Filtration Efficiency** | 99.9%, 3 lots | 99.9%, 3 lots | Meet the ASTM F2100 Requirements for Level 3 Classification | ≥98% | PASS |
| **Differential Pressure** | 3.4, 3.0, 3.0 $mmH_2O/cm^2$ | 4.1, 3.4, 3.4 $mmH_2O/cm^2$ | Meet the ASTM F2100 Requirements for Level 3 Classification | ＜6.0 | PASS |
| **Flammability** | Class 1 | Class 1 | Class 1 | Class 1 | PASS |

**G. Summary of Non-Clinical Test**

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same to the predicate device. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: *Surgical Masks – Premarket Notification [510(k)] Submission* issued on March 5, 2004:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ASTM F2100, Standard Specification for Performance of Materials Used In Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks To Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume At A Known Velocity);
- EN 14683, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles;

**H. Summary of Clinical Test**

No clinical study is included in this submission.

**I. Conclusion**

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K133070.